

F. No. DC-DT-15011(11)/63/2024
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization

Dated: 27.03.2025

Office Memorandum

Subject: Exemption of sampling & testing of orphan drugs at CDSCO Port offices - Regarding.

This office has received representations from the various associations and importers of Drugs organizations involved in the import and marketing of life saving orphan drugs in the country. "Orphan drug" is defined as per clause (x) of rule 2 of New Drugs & Clinical Trial Rules 2019, means a drug intended to treat a condition which affects not more than five lakh persons in India.

Various challenges encountered drug sampling and testing of orphan drugs at various port office of CDSCO have been brought to the notice, such as small volume, high cost, requirement of specialized testing equipments and unavailability reference standards & testing methods at testing laboratories. These challenges may lead to delay the availability of such lifesaving orphan drugs to needy patients. Procedure for sampling & testing during import of drugs at various port offices of CDSCO has been defined in the Guidance Document for Zonal, Sub-zonal & Port Offices (Revision: 01, 2024) dated 12.09.2024.

Considering the various representations received in the matter and to stream line the procedure for release of orphan drugs it has been decided that such consignment shall be released by the CDSCO Port offices on the basis of legal undertaking submitted by the importer stating that required quantity of sample shall be forwarded to the concerned laboratory and test report shall be submitted to respective port office within 15 days of receiving from the laboratory.

Yours faithfully



Dr. Rajeev Singh Raghuwanshi
Drugs Controller General of India

To:

1. All Zonal and Sub-zonal offices of CDSCO
2. All Port offices (Air/Sea) of CDSCO
3. All Stake holders through CDSCO Website (for information)